REMARKS

Drawings

The drawings have been objected to for failing to show an embodiment of the invention "with only one transverse projection". (See page 1). However, the Applicant notes that the claims recite "at least one but no more than two transverse projections". The Applicant further notes that the drawings figures illustrate an instrument having two transverse projections, and that an instrument having two transverse projections clearly falls within the scope of the recitation of "at least one" transverse projection. Accordingly, the disclosed instrument is submitted to fall within the scope of the claimed invention. The objection to the drawings appears to be based on an interpretation of the phrase "at least one" to mean "only one" or "a single one". However, the Applicant submits that such an interpretation is incorrect. Nevertheless, in order to advance prosecution of the subject application, the Applicant has amended independent claims 59, 66 and 69 to remove the recitation of "at least one" transverse projection. Accordingly, the objections to the drawings are deemed moot and withdrawal of the same is respectfully requested.

Claim Rejections – 35 USC §112, First Paragraph

Claims 66-67, 69 and 94-103 have been rejected under 35 USC §112, first paragraph, as failing to comply with the written description requirement. Specifically, the rejection is based on the asserted that "[t]he disclose does not show one transverse projection (sic) with two slots". (See page 3). However, as indicated above, the Applicant submits that an instrument having two transverse projections clearly falls within the scope of the recitation of "at least one" transverse projection. Accordingly, the disclosed instrument is submitted to clearly fall within the scope of the claimed invention. Furthermore, the written description specifically discloses that the instrument includes "laterally extending projections or protrusions 198*a*, 198*b*", and that "the deformed configuration of instrument 20 may define any number of laterally extending projections, including a single projection or three or more projections". (See page 20, lines 7-9; emphasis added). Nevertheless, in order to advance prosecution of the subject application, the Applicant has amended independent claims 59, 66 and 69 to remove the recitation of "at least one" transverse projection. Accordingly, the claim rejections based on 35 USC §112, first paragraph are deemed moot and withdrawal of the same is respectfully requested.

Claim Rejections – 35 USC §103

Claims 55-63, 65-70, 74 and 94-103 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,522,790 to Moll et al. (hereafter "Moll").

Claim Amendments

As indicated above, independent claims 59, 66 and 69 have been amended to remove the recitation of "at least one" transverse projection to address the informalities set forth in the Office Action. However, the Applicant submits that such amendments do not change the scope of the claims with regard to patentability over Moll, and therefore do not raise any new issues relating to patentability that would require further consideration and/or searching.

Arguments in Support of Patentability

The Applicant notes that MPEP §706.02(j) states that "[t]o support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." (Citations omitted; emphasis added). Additionally, MPEP §2142 states that "[t]he examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness", and that "[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in KSR International Co. v. Teleflex Inc. noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Federal Circuit has stated that 'rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" (Citations omitted; emphasis added).

Furthermore, it is well established that "[t]o establish a *prima facie* case of obviousness, . . . there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. . . . The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." Additionally, a "prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." Manual of Patent Examining Procedure (MPEP) § 2141.02.VI (emphasis in original; citations omitted). As

a corollary, the Patent Office recognizes that "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." MPEP § 2143.01.V (citations omitted).

Each of the pending claims have been rejected as being unpatentable over a single patent reference; namely, U.S. Patent No. 5,522,790 to Moll et al. The Office Action asserts that the instrument illustrated in Figures 12F and 12G of Moll includes a deformable distal end portion that is outwardly deformed to "define transverse projections, each of the transverse projections arranged along a single transverse axis", and . . . extends in a uni-lateral direction aligned with the single transverse axis". (See page 4, lines 2-6; emphasis added). The Office Action admits that "Moll et al. does (sic) not explicitly teach two oppositely spaced transverse projections", but asserts that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the Moll et al device with two, oppositely spaced projections, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art". (See page 6, lines 3-7). For at least the reasons set forth below, the Applicant submits that the grounds set forth in the Office Action with regard to independent claims 59, 66 and 69 do not set forth a proper basis to establish a *prima facia* case of obviousness.

Each of the independent claims 59, 66 and 69 recites, among other elements and features, an elongate member including a deformable distal portion that is outwardly deformed to an expanded configuration that defines "no more than two transverse projections", with "each of said transverse projections arranged along a single transverse axis, and wherein formation of said transverse projections is directionally controlled such that each of said transverse projections extends in a uni-axial direction aligned with said single transverse axis".

As shown in Figure 12F and 12G of Moll, the endoscope 201 comprises a tubular optical assembly 203 like those used in conventional optical/video endoscopes, and an expandable retractor 223 including a fixed hub 225 and a slidable hub 227 that are interconnected by a plurality of strips or wires 229. The retractor 223 is expanded from the collapsed condition illustrated in Figure 12F to the expanded condition illustrated in Figure 12G by sliding the slidable hub 227 axially along the optical assembly 203, which in turn causes the strips 229 to move radially outwards to form the spherical-shaped expanded structure shown in FIG. 12G.

Moll teaches that "[i]n its expanded condition, the expandable mechanical retractor retracts organs obstructing the field of view from the distal end of the optical assembly" and that the expanded retractor "retracts organs or tissues that would otherwise obstruct the view from the optical assembly". (See column 23, lines 62-64 and column 24, lines 7-9; emphasis added).

As an initial matter, Moll discloses an endoscope configured to retractor organs or soft tissues to provide a work space or field of view for observing adjacent organs or tissues, and not to bear against vertebral bone and uni-axially displace a spinal structure, as recited in independent claims 59, 66 and 69. In the illustrated embodiment of the endoscope, the retractor 223 includes at least twelve (12) strips 229 that are outwardly expanded in a radial direction to form a spherical-shaped work space or field of view for observing adjacent organs or tissues via the optical assembly 203. (See Figure 12G). Even assuming arguendo that the radially expanded strips 229 could be construed to comprise transverse projections, as admitted in the Office Action, the retractor 223 does not satisfy the recitation of "no more than two transverse projections" that are each "arranged along a single transverse axis", and the radially expanded strips 229 do not extend "in a uni-axial direction along with said single transverse axis", as recited in independent claims 59, 66 and 69. To the contrary, the retractor 223 includes a significantly greater number of strips 229 (i.e., twelve strips) that are arranged along multiple transverse axes, extend in multiple radial directions and which are clearly not aligned with a single transverse axis. Accordingly, Moll fails to satisfy each of the elements and features recited in independent claims 59, 66 and 69.

Moreover, one of ordinary skill in the art would not be motivated to modify the endoscope 201 disclosed in Moll to arrange the expanded strips 229 along a single transverse axis so as to extend in a uni-axial direction. Indeed, as indicated above, it is well established that "[t]o establish a *prima facie* case of obviousness, . . . there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. . . ." Additionally, a "prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." Manual of Patent Examining Procedure (MPEP) § 2141.02.VI (emphasis in original; citations omitted). As a corollary, the Patent Office recognizes that "[i]f the proposed modification or combination of the prior art

would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." MPEP § 2143.01.V (citations omitted).

As indicated above, Moll discloses an endoscope 201 including a retractor 223 that is expanded to retract organs obstructing the field of view from the distal end of the optical assembly" and that the expanded retractor 223 "retracts organs or tissues that would otherwise obstruct the view from the optical assembly". The expanded retractor 223 thereby retracts the organs or soft tissues to provide a spherical work space or field of view such that adjacent organs or tissues can be observed and directly visualized via the optical assembly 203 positioned within the spherical work space formed by the radially expanded strips 229. As should be appreciated, limiting the number of expanded strips 229 to "no more than two" and positioning each of the radially expanded strips 229 "along a single transverse axis" so as to extend "in a uni-axial direction aligned with said single transverse axis" would not form a work space or field of view between the expanded strips 229 sufficient to allow for observation and direct visualization of adjacent organs and tissues via the optical assembly 203. As should be appreciated, limiting the number of expanded strips 229 to "no more than two" and aligning the strips "along a single transverse axis" would provide a very narrow work space aligned along a single axis, and the only structures that would be observable by the optical assembly 203 would be the inner surfaces of the strips 229. Such a result would obstruct observation/viewing of adjacent organs/tissues by the optical assembly 203, and the Moll device would therefore not function as intended to provide unobstructed observation and visualization of adjacent organs and tissues via the optical assembly 203 positioned within the spherical work space formed by the radially expanded strips 229.

When the teachings of Moll are taken as a whole and considered in their entirety, one of ordinary skill in the art would not limit the number of strips to "no more than two", and would not arrange each of the strips 229 "along a single transverse axis" so as to extend "in a uni-axial direction", for to do so would not provide the unobstructed spherical work space or field of view necessary to properly observe adjacent organs/tissues by the optical assembly 203. Accordingly, one of ordinary skill in the art would not be motivated to modify the Moll device to arrive at the invention recited in independent claims 59, 66 and 69. As a result, a *prima facie* case of obviousness is not apparent with regard to the rejection of the independent claims 59, 66 and 69

as being unpatentable over Moll. For at least the reasons set forth above, independent claims 59, 66 and 69 are submitted to be patentable over Moll. The Applicant therefore respectfully requests withdrawal of the rejection of independent claims 59, 66 and 69 and allowance of the same.

Furthermore, independent claims 66 and 69 additionally recite that the deformable distal portion includes a pair of longitudinally extending slots that define a longitudinally extending flexible strip of material therebetween that is deformed to define one of the transverse projections, with "at least one of said longitudinally extending slots having a narrowed area and a widened area extending axially from said narrowed area, said widened area having a greater width relative to said narrowed area to provide said flexible strip of material with a narrowed width which defines a flexion point to control outward deformation of said flexible strip of material to said outwardly buckled configuration".

As an initial matter, the Applicant notes that the Office Action fails to in any way address how Moll teaches or suggests the above-identified features recited in independent claims 66 and 69. Indeed, the Office Action does not even mention or in any way refer to the terms "narrowed area" or "widened area" in association with the regions between the strips 229, and does not mention or in any way indicate how these features provide the strips 229 with "a narrowed width which defines a flexion point to control outward deformation". As indicated above, to support a *prima facia* case of obviousness "the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references". Furthermore, "[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious" and "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" (Citations omitted; emphasis added).

The Applicant submits that the Office Action does not set forth "a clear articulation of the reasons" nor "articulated reasoning with some rational underpinning" that would support a legal conclusion as to how Moll teaches or suggests "at least one of said longitudinally extending slots having a narrowed area and a widened area extending axially from said narrowed area, said widened area having a greater width relative to said narrowed area to provide said flexible strip of material with a narrowed width which defines a flexion point to control outward deformation of said flexible strip of material to said outwardly buckled configuration", as recited in

independent claims 66 and 69. In and of itself, this reason alone supports the Applicant's position that a *prima facia* case of obviousness has not been established with regard to independent claims 66 and 69.

Moreover, the Applicant notes that the strips 229 of the retractor 223 are formed by "making a number of longitudinal cuts almost from end-to-end of a tube of suitable malleable material ". (See column 18, line 66 to column 19, line 1). The Applicant further notes that the straight lines located just above the fixed hub 225 constitute longitudinal cuts formed along the length of the retractor 223 to form the individual strips 229. Even assuming arguendo that these longitudinal cuts could be construed as "longitudinally extending slots", the longitudinal cuts do not have "a narrowed area and a widened area extending axially from said narrowed area, said widened area having a greater width relative to said narrowed area". To the contrary, the longitudinal cuts are straight and have a uniform shape and width, and do not in any way define a "widened area" having a greater width relative to "a narrowed area". Moreover, the longitudinal cuts do not provide the strips 229 with "a narrowed width which defines a flexion point to control outward deformation". To the contrary, the strips 229 each have a rectangular-shape having a uniform shape and width, and Moll does not in any way teach or suggest that the strips 229 are provided with a narrowed width that defines a flexion point.

Accordingly, independent claims 66 and 69 are submitted to be patentable over Moll for these additional reasons as well. The Applicant therefore respectfully requests withdrawal of the rejection of independent claims 66 and 69 and allowance of the same.

Claims 55-58, 60-63, 65, 68, 71-74 and 94-97 depend either directly or indirectly from independent claim 59 and are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claim 59. However, further reasons support the patentability of the claims depending from independent claim 59.

For example, claim 94 recites subject matter similar to that discussed immediately above with regard to independent claims 66 and 69. Specifically, claim 94 recites that the deformable distal portion includes a pair of longitudinally extending slots that define a longitudinally extending flexible strip of material therebetween that is deformed to define one of the transverse projections, with "at least one of said longitudinally extending slots having a narrowed area and a widened area extending axially from said narrowed area, said widened area having a greater width relative to said narrowed area to provide said flexible strip of material with a narrowed

width which defines a flexion point to control outward deformation of said flexible strip of material to said outwardly buckled configuration". As discussed in detail above with regard to independent claims 66 and 69, Moll fails to teach or suggest these features, and the Office Action does not set forth articulated reasoning with rational underpinning that would support a legal conclusion as to how Moll teaches or suggests these features.

Moreover, claim 95 recites that "said widened area of said slot is defined by an arcuate portion of said slot", claim 96 recites that "said slot has first and second widened areas with said narrowed area positioned between said first and second widened areas to provide said slot with an hour-glass shape", and claim 97 further recites that "said hour-glass shape is defined by a series of arcuate portions of said slot extending along said longitudinal axis". Once again, the longitudinal cuts between the strips 229 are straight and have a uniform shape and width, and do not in any way define "an arcuate portion" or "an hour-glass shape" defined by a series of arcuate portions. If the rejections of claims 95-97 are maintained, the Applicant respectfully requests citation to specific portions of the Moll reference which disclose or suggest these recited features. The Applicant notes that the current grounds of rejection of these claims are merely restatements of the claim language along with a conclusion that the recited features would have been obvious in view of Moll. However, such grounds do not provide "a clear articulation of the reasons" or "articulated reasoning with some rational underpinning" that would support a legal conclusion as to how Moll teaches or suggests the features recited in claims 95-97.

Additionally, claim 63 further recites an actuator mechanism comprising a first portion coupled to an actuator member and a second portion coupled to the sleeve member and engaged with the first portion, and "wherein relative rotation between said first and second portions imparts relative linear displacement between said actuator member and said sleeve member to cause said distal portion of said sleeve member to reform from said initial configuration toward said expanded configuration". Even assuming arguendo that the optics assembly 203 could be construed as a second portion of an actuator mechanism that is coupled to the retractor 223, Moll fails to disclose or suggest "a first portion coupled to an actuator member". Indeed, Moll does not discuss any type of actuator mechanism "wherein relative rotation between said first and second portions imparts relative linear displacement between said actuator member and said sleeve member" to transition a deformable distal portion to an expanded configuration. If the

rejection of claim 63 is maintained, the Applicant respectfully requests citation to a specific portion of Moll which discloses or suggests these recited features.

Claim 74 further recites that the deformable distal portion is "at least partially formed of a shape-memory material, said deformable distal portion being reformed from said initial configuration toward said expanded configuration in response to the imposition of stress and automatically reformed back toward said initial configuration upon removal of said stress". The Applicant has reviewed the Moll reference and has not found any reference whatsoever as to any portion of the retractor 223 being formed of a shape-memory material. Once again, if the rejection of claim 74 is maintained, the Applicant respectfully requests citation to a specific portion of Moll which discloses or suggests this feature.

Claims 67 and 98-100 depend either directly or indirectly from independent claim 66, and claims 70 and 101-103 depend either directly or indirectly from independent claim 69. These dependent claims are submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claims 66 and 69. However, further reasons support the patentability of dependent claims 67, 70 and 98-103. For example, claims 70 recites that the predetermined shape of the longitudinal slot is "at least partially comprised of an hour-glass shape", claims 98 and 101 recites that "said widened area of said slot is defined by an arcuate portion of said slot", claims 99 and 102 recites that "said slot has first and second widened areas with said narrowed area positioned between said first and second widened areas to provide said slot with an hour-glass shape", and claims 100 and 103 further recites that "said hour-glass shape is defined by a series of arcuate portions of said slot extending along said longitudinal axis".

As indicated above, the longitudinal cuts between the strips 229 are straight and have a uniform shape and width, and do not in any way define "an arcuate portion" or "an hour-glass shape" defined by a series of arcuate portions. If the rejections of claims 67, 70 and 98-103 are maintained, the Applicant respectfully requests citation to specific portions of the Moll reference which disclose or suggest these features. The Applicant notes that the current grounds of rejection of these claims are merely restatements of the claim language. However, such grounds do not provide "a clear articulation of the reasons" or "articulated reasoning with some rational underpinning" that would support a legal conclusion as to how Moll teaches or suggests the features recited in claims 67, 70 and 98-103.

CONCLUSION

The Applicant respectfully requests entry of this response to the non-final Office Action and consideration and allowance of the present application including pending claims 55-63, 65-74 and 94-103. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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